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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): TNI 2-011

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on 06/17/2008 - Electronically

Signature /Jane Keeney/

Typed or printed name Jane Keeney

Application Number	Filed
10/807620	03/24/2004

First Named Inventor: Jessie L.-S. Au

Art Unit	Examiner
1614	James D. Anderson

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 13-4830.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/J.K. Mueller, Jr./
Signature

Jerry K. Mueller, Jr.
Typed or printed name

614-436-0600
Telephone number

June 17, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Jessie L.S.-Au, *et al.*
Serial No.	:	10/807,620
Filed:	:	March 24, 2004
For:	:	METHODS AND COMPOSITIONS TO DETERMINE THE CHEMOSENSITIZING DOSE OF SURAMIN USED IN COMBINATION THERAPY
TC/AU	:	1614
Examiner	:	James D. Anderson
Attorney Docket No.	:	TNI 2-011

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

DuPont discloses an anti-tumor composition composed of an anti-neoplastic agent and shark cartilage. One of the listed anti- neoplastic compositions is suramin. Not disclosed by DuPont is the fact that use of therapeutic (high) doses of suramin yield concentrations between about 300 to about 650 μM, which do not enhance the efficacy of chemotherapeutics and only enhanced the toxicity of chemotherapy. In fact, it was Applicants who showed that only low doses of suramin, which yield circulating concentrations of below about 200 μM (*e.g.*, between about 10 to about 50 μM plasma concentrations) when a chemotherapeutic agent (*e.g.*, paclitaxel) was present in the plasma at therapeutically significant levels, enhanced the efficacy of chemotherapy in tumor-bearing animals. Applicants' discovery is diametrically the opposite of the teachings of DuPont.

With respect to "print instructions", it is material error to ignore printed instructions in applying Section 103(a), even it the printed matter does not constitute patentable subject matter. *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983). More recently, the same Court stated that printed matter has patentable significance if there exists any new and unobvious functional relationship between the printed matter and the composition of the kit. *In re Ngai*, 35 USPQ2d 1384 (Fed. Cir. 2004). The MPEP expressly recognizes the vitality of the *Gulack* decision at MPEP § 2112.01 by stating, *inter alia*: "III. ... [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate."

Applying that Court and MPEP sanctioned standard to the kit subject matter of claim 22, the printed instructions provide a new and unobvious functional relationship between suramin and the printed instructions. That is, the printed instructions inform the user that a patient must have a low dose of circulating suramin (< 200 μM) at which time a chemotherapeutic is administered to the patient for enhancement of the chemotherapeutic activity. Moreover, the printed instructions also provide an algorithm for the physician to use in determining the proper dose of suramin for each patient based on criteria not taught by DuPont or any other reference. Such criteria include the following elements from claim 22:

(b1) determining the squared value of the body surface area (BSA) of said patient;

(b2) determining the time elapsed, in days, since the initiation of the last suramin treatment; and

(b3) calculating the dose of low dose suramin using a nomogram that shows the dose according to the parameters of squared value of body surface, and elapsed days since last suramin treatment.

All other claims include the limitations of claim 22. Claim 26 further discloses a particular cytotoxic agent. Claims 27 and 28 further disclose particular ranges of circulating suramin. A nomogram is recited in claim 30. Additional cytotoxic agents are disclosed in clam 31. Claim 32 further discloses a time period over which the suramin is administered to the patient. Claim 33 also discloses a time period over which particular amounts of suramin are administered to the patient. Finally, claim 34 further discloses another treatment regimen.

None of these functional relationships between suramin and the printed instructions are disclosed in the art.

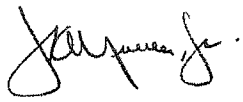
In support of this position a declaration dated March 6, 2008 of Dr. Au, a co-inventor of the subject matter disclosed in the above-identified application, was submitted. Dr. Au elegantly relates the research that led to the subject being claimed. In particular, Dr. Au supports each every point argued above. Indeed, there is the requisite functional relationship between suramin and the printed instructions. Moreover, in Dr. Au's expert opinion, the functional relationship is non-obvious.

The printed instructions, then, satisfy the *Gulack* test as approved of in the MPEP and should not have been ignored by the Examiner. It is noted finally that even Ngai's ultimately issued patent contained a "kit" claim.

Conclusion

Applicants respectfully request that the final rejection of the Examiner be reversed and that the claims be allowed and this application passed to issue.

Respectfully submitted,



Date: 17 June 2008

Jerry K. Mueller, Jr.
Reg. No. 27,576
MUELLER SMITH
A Legal Professional Association
Mueller-Smith Building
7700 Rivers Edge Drive
Columbus, Ohio 43235-1355
Tel.: 614-436-0600
Fax: 614-436-0057
email: *smueller@muellersmith.com*